K133290

MAY 0 1 2014

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Pharmaceuticals

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510(k) Summary

Date Prepared: 30th April 2014

Submitter:
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Submission Correspondent:
Aaron Wyse
Senior Director of Regulatory Affairs
Tel: +353 (0) 9066 90661
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Proprietary Name: Collacare Dental

Common Name: Collagen dental matrix

Device Classification:

Product Code:	KGN
Classification Name:	Wound Dressing, Collagen
Regulatory Class:	Unclassified

Predicate devices:
Collacare Dental (K110388)
Collagen Wound Matrix-Oral (K122115)

Intended Use:

Collacare Dental is indicated for the management of oral wounds and sores, including:

- denture sores
- oral ulcers (non-infected or viral)
- periodontal surgical wounds
- suture sites
- burns
- surgical wounds and traumatic wounds

Description:

Collacare Dental is a collagen matrix, conformable and resorbable, manufactured from purified type I collagen derived from bovine Achilles tendon. Collacare Dental is supplied sterile and non-pyrogenic, in various sizes, and for single use only. Sizes available include the following:
Dental Sponges: 3.6cm x 1.8cm, 2.5cm x 2.5cm and 2.5cm x 5cm
Dental Cone: Height-17mm Ø Top – 10mm Ø Bottom – 14mm

Statement of Substantial Equivalence:

Collacare Dental is substantially equivalent in materials of construction and indications to Collacare Dental (K110388) and Collagen Wound Matrix-Oral (K122115)

Feature	Collacare Dental	Collacare Dental	Collagen Wound Dressing-Oral
Manufacturer	Syntacoll GmbH	Syntacoll GmbH	Collagen Matrix Inc.
510(k) number	K110388	K133290	K122115
Indications for Use	Collacare Dental is indicated for the management of oral wounds and sores, including: • denture sores • oral ulcers (non-infected or viral) • periodontal surgical wounds • suture sites • burns • surgical wounds • traumatic wounds	Collacare Dental is indicated for the management of oral wounds and sores, including: • denture sores • oral ulcers (non-infected or viral) • periodontal surgical wounds • suture sites • burns • surgical wounds • traumatic wounds	Collagen Wound Dressing - Oral is indicated for the management of oral wounds and sores, including: · Denture sores · Oral ulcers (non-infected or viral); · Periodontal surgical wounds · Suture sites · Burns · Extraction sites · Surgical wounds · Traumatic wounds
Materials	Type I Collagen	Type I Collagen	Type I Collagen
Collagen Source	Bovine Achilles tendon	Bovine Achilles tendon	Porcine Achilles tendon
Biodegradable	Yes	Yes	Yes
Biocompatible	Yes	Yes	Yes
Non- Pyrogenic	Yes	Yes	Yes
Sterile	Yes - Irradiation	Yes - Irradiation	Yes - Irradiation
Sizes	Matrix: 2.5cm x 2.5cm and 2.5cm x 5cm	Matrix: 3.6cm x 1.8cm 2.5cm x 2.5cm and 2.5cm x 5cm Plug: Height-17mm Ø Top – 10mm Ø Bottom – 14mm	Matrix: 2.5cm x 7.5cm, 2.cm x 4cm Plug: 1cm x 2 cm
Storage Conditions	Room temperature less than 25°C	Room temperature less than 25°C	The product should be stored at room temperature. Avoid excessive heat and humidity.

Summary of Performance Testing:

There are no new biocompatibility issues arising with the use of Collacare Dental as the materials of construction and finished product material match that of Collacare Dental (K110388). Biocompatibility testing undertaken included cytotoxicity, sensitization, irritation, systemic toxicity, and pyrogenicity.

Collagen type and purity evaluated to show no denaturing during manufacturing process

Viral reduction assessments conducted to show viral deactivation within acceptable safety range.

Conclusion:
Collacare Dental is substantially equivalent to the predicate devices delineated in this submission and meets the requirements for premarket notification as defined in CFR21, Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 1, 2014

Innocoll Pharmaceuticals Limited
Mr. Aaron Wyse
Senior Director of Regulatory Affairs
Midland Innovation and Research Centre
Dublin Road, Athlone
Co. Westmeath, Ireland

Re: K133290
Trade/Device Name: Collacare Dental
Regulatory Class: Unclassified
Product Code: KGN
Dated: March 20, 2014
Received: April 1, 2014

Dear Mr. Wyse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K133290

Device Name: Collacare Dental

Indications For Use:

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- denture sores
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- suture sites
- burns
- surgical wounds and traumatic wounds

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Sheena A. Green -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)